

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 09 SEP 2005



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Applicant's or agent's file reference 21019WO/P0/		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/NL 03/00473	International filing date (day/month/year) 26.06.2003	Priority date (day/month/year) 26.06.2003	
International Patent Classification (IPC) or both national classification and IPC B29C67/24			
Applicant STICHTING DUTCH POLYMER INSTITUTE et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  24.01.2005	Date of completion of this report  08.09.2005
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Attalla, G  Telephone No. +49 89 2399-6004 

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/NL 03/00473

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

### Description, Pages

1-8 as originally filed

### Claims, Numbers

1-14 received on 11.03.2005 with letter of 08.03.2005

### Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-14
	No: Claims	
Inventive step (IS)	Yes: Claims	1-14
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations  
**see separate sheet**

**Re Item V**

1. The process of claim 1 is novel and it is considered to involve an inventive step for the following reasons.

The problem solved by the claimed method is to increase the processability of UHMWPE. This is obtained by keeping the level of entanglement as low as possible during shaping, by heating the material above melting point at a limited heating rate and, after shaping, bringing the material to its fully entangled state.

No document of the prior art discloses or even only suggests the process of claim 1. Therefore the subject matter of claim 1 meets the requirements of Art. 33 PCT.

2. The method according to claim 1 allows to obtain a shaped part which is essentially free of grain boundaries. Therefore the resulting product appears to be distinguishable from a moulded product obtained by a conventional method (e.g. as described in claim 1 of WO-A-03037590). Thus, also the subject matter of independent claims 12 and 13 is to be considered to meet the requirements of Art. 33 PCT.

3. Claims 2 to 11 and claim 13 are dependent respectively upon claim 1 or claim 13 and, as such, also meet the requirements of the PCT with respect to novelty and inventive step.

4. In claim 2 it is not clear the meaning of "as of a temperature of 350 K". Therefore the clarity requirement of Art. 84 EPC is not fulfilled.

### NEW SET OF CLAIMS

1. Process for the preparation of a shaped part of an ultrahigh molecular weight polyethylene (UHMWPE) by heating the UHMWPE to a temperature above the melting temperature, shaping the resulting melt, and cooling the melt to a temperature below the melting temperature, wherein
  - a) the UHMWPE has a weight average molecular weight (Mw) of at least  $1 \cdot 10^6$  g/mol,
  - b) during the shaping the storage plateau modulus ( $G^*$ ) of the UHMWPE is kept at a value of at most 1.5 MPa,
  - c) whereafter, before the cooling, the  $G^*$  is raised to its final value.
2. Process according to claim 1, wherein  $\Theta$  is at most 1 K/minute, as of a temperature of 350K.
3. Process according to claim 2, wherein the heating rate  $\Theta$  is at most 5 K/minute.
4. Process according to claim 2, wherein the MWD is between and inclusive 1.2 – 3.0.
5. Process according to anyone of claims 1-3, wherein the initial value of  $G^*$  is at most 0.75 MPa.
6. Process according to anyone of claims 1-5, wherein  $G^*$  builds up to a value of 1.5 MPa at a speed ( $\Psi$ ) less than 3 MPa/hour.
7. Process according to claim 6, wherein  $\Psi$  is less than 0.5 MPa/hour.
8. Process according to anyone of claims 1-7, wherein the UHMWPE is obtained through a solution or suspension polymerization at a temperature of between 225 and 325 K, using an unsupported catalyst in a concentration of less than  $1 \cdot 10^{-4}$  mol/L.
9. Process according to anyone of claims 1-8, wherein the UHMWPE is either a homopolymer of ethylene, or a copolymer of ethylene with another  $\alpha$ -olefin or cyclic olefin.
10. Process according to claim 8, wherein the polymerisation takes place at a temperature between and inclusive 260 and 305 K.
11. Process according to anyone of claims 1-10, wherein the UHMWPE is annealed during the heating, at a temperature of not less than 398K and not more than 410K.
12. Essentially grain boundary free shaped part, obtainable with a process according to anyone of claims 1-11.

nted: 15-03-2005

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Enclosure to letter dated 08 March 2005 concerning Patent Appln. No.  
PCT/NL03/00473; -Stichting Dutch Polymer Institute-; ref: 21019WO/P0.

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NEW SET OF CLAIMS (continued)

13. Use of a shaped part according to claim 12, or prepared according to anyone of claims 1-11, in a medical application.
14. Use according to claim 13, wherein the shaped part is an element of a hip or knee prosthesis.